



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

August 22, 2014

GKC Manufacturing Pty Ltd.  
c/o Ms. Marie Schroeder  
Quintiles Consulting  
1801 Rockville Pike Suite 300  
Rockville, MD 20852

Re: K140086

Trade/Device Name: Personal Kinetigraph (PKG) System  
Regulation Number: 21 CFR 882.1950  
Regulation Name: Tremor Transducer  
Regulatory Class: Class II  
Product Code: GYD, ISD, NXQ  
Dated: July 22, 2014  
Received: July 24, 2014

Dear Ms. Schroeder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Felipe Aguel -S

for Carlos L. Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

510(k) Number (*if known*)

K140086

Device Name

Personal Kinetigraph (PKG) System

### Indications for Use (*Describe*)

The Personal Kinetigraph (PKG) System is intended to quantify kinematics of movement disorder symptoms in conditions such as Parkinson's disease, including tremor, bradykinesia and dyskinesia. It includes a medication reminder, an event marker and is intended to monitor activity associated with movement during sleep. The device is indicated for use in individuals 46 to 83 years of age.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

**Felipe Aguel -S** Date: 2014.08.22 10:36:26  
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## **Section 5**

### **510 (k) Summary**

**Preparation Date:** January 13, 2014

**Applicant/Sponsor:** GKC Manufacturing Pty Ltd  
Level 6, 530 Collins Street  
Melbourne, Victoria 3000  
Australia

**Contact Person:** Andrew Maxwell  
Managing Director  
Tel: +61 3 9605 0034

**Trade Name:** Personal Kinetigraph (PKG) System

**Common Name:** Movement Disorder Monitoring System

**Classification Name:** Tremor Transducer  
21 CFR 882.1950

**Product Code:** GYD, ISD, NXQ

**Device Class:** II

**Predicate Device:** MM-1 Movement Monitor  
Axon Instruments, Inc.  
510(k) Number K971318

Kinesia  
Great Lakes NeuroTechnologies  
(formerly Cleveland Medical Devices Inc.)  
510(k) Number K063872

ActiTrainer  
ActiGraph, LLC  
510(k) Number K080545

Pill Phone  
Vocel  
510(k) Number K060298

**Device Description:**

The Personal Kinetigraph (PKG) System is a small, wrist-worn activity monitor that continuously records and quantifies the kinematics of movement disorder symptoms over a 6 to 10 day period in movement disorder conditions such as Parkinson's disease. A report is produced using the recorded data that objectively distinguishes the movement patterns consistent with tremor, bradykinesia, dyskinesia and immobility. This information can be used by the clinician to assess the extent and severity of movement disorder symptoms, and how they vary throughout the day, and from day to day. The PKG Data Logger has a medication reminder to indicate to the patient that it is time to take their medication, and an event marker for the patient to record when they have taken their prescribed medication.

**Indications for Use:**

The Personal Kinetigraph (PKG) System is intended to quantify kinematics of movement disorder symptoms in conditions such as Parkinson's disease, including tremor, bradykinesia and dyskinesia. It includes a medication reminder, an event marker and is intended to monitor activity associated with movement during sleep. The device is indicated for use in individuals 46 to 83 years of age.

**Comparison of Technological Characteristics:**

The Technological Characteristics of the Personal Kinetigraph (PKG) System comprising the logger hardware and system software, medication reminder, tremor and monitoring activity associated with movement during sleep are the same as the predicates except for minor differences that could not impact safety or effectiveness.

- The data logger hardware and system software, incorporating wristwatch-type design, the accelerometer sensor, internal data storage, transmission of data to a computer, and presentation of data are substantially equivalent to the Kinesia, Acti-Trainer, and the MM-1.
- The medication reminder and event marker are substantially equivalent to the Kinesia and Pill Phone
- The method for recording tremor is substantially equivalent to the MM-1 and Kinesia
- The method for monitoring the activity associated with movement during sleep is substantially equivalent to the ActiTrainer.

The technological characteristics of bradykinesia and dyskinesia are the not the same as the predicates but do not raise new types of safety or effectiveness questions and the method used correlates with accepted scientific methods, such as the UPDRS III.

**Substantial Equivalence:**

While the Personal Kinetigraph (PKG) System's Indications for Use are not identical to each of the Indications for Use of the predicate devices, the minor differences do not alter the intended effects or impact safety or effectiveness, as they are achieved using the same mechanisms of action and the same types of data. Moreover, the minor differences in the Indications for Use of the Personal Kinetigraph (PKG) System do not change the types or increase the level of risk as compared to the predicate devices.

The Personal Kinetigraph (PKG) System therefore is considered substantially equivalent to its predicates.